November 28, 2001

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT REPORT NO. OAR-02-01, "OBSERVATION AUDIT OF THE BECHTEL SAIC COMPANY, LLC, AUDIT NO. BSC-SA-01-030 OF LAMBDA RESEARCH, INC."

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (No. OAR-02-01) of the U.S. Department of Energy's (DOE's), Office of Civilian Radioactive Waste Management (OCRWM), Management and Operating Contractor, Bechtel SAIC Company, LLC (BSC), Quality Assurance (QA), audit of Lambda Research, Inc. (Lambda). This audit was conducted on October 31 and November 1, 2001, at Lambda facilities in Cincinnati, Ohio.

The purpose of this audit was to evaluate the effectiveness of the implementation of Lambda's QA Manual (QAM) and to determine if applicable requirements of the OCRWM Quality Assurance Program Description (QARD) were being met. The scope of the audit included evaluating the implementation of the QARD and QAM for the residual stress measurements of welded mockups supporting the design of the high-level waste containers for the proposed repository at Yucca Mountain, Nevada.

The NRC observers (observers) determined that this audit was effective in identifying potential deficiencies and recommending improvements for the Lambda activities reviewed. During the conduct of the audit, both the BSC audit team (audit team) and the observers reviewed applicable documents, procedures, and activities within the audit's scope.

Also, the audit team and observers reviewed and observed ongoing testing activities. The audit team identified potential deficiencies in training, calibrations, document control, software verification and validation, and corrective action. The staff believes that this BSC audit was well-planned, thorough, and adequately evaluated Lambda's residual stress measurement activities.

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. Notwithstanding the audit team's findings, the staff believes that Lambda is properly controlling residual stress measurement activities within the scope of the audit. The staff will continue to interface with OCRWM and follow the progress that Lambda is making to address the issues identified during this audit.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter at (301) 415-6684.

Sincerely,

/RA/

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-02-01, "Observation Audit
of the Bechtel SAIC Company, LLC,
Audit No. BSC-SA-01-030 of Lambda Research, Inc."

CC: See attached list

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Letter to R. Milner from C.W. Reamer dated November 28, 2001

cc:

R. Loux, State of Nevada
S. Frishman, State of Nevada
L. Barrett, DOE/Washington, DC
A. Brownstein, DOE/Washington, DC
S. Hanauer, DOE/Washington, DC
C. Einberg, DOE/Washington, DC
J. Carlson, DOE/Washington, DC
N. Slater, DOE/Washington, DC
A. Gil, YMPO
R. Dyer, YMPO
S. Brocoum, YMPO
R. Davis, YMPO
S. Mellington, YMPO
C. Hanlon, YMPO
T. Gunter, YMPO
K. Hess, BSC
D. Krisha, BSC
S. Cereghina, BSC
N. Williams, BSC
M. Voegele, BSC/SAIC
R. Henning, BSC
B. Price, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
I. Navis, Clark County, NV
E. von Tiesenhausen, Clark County, NV
A. Kalt, Churchill County, NV
G. McCorkell, Esmeralda County, NV
L. Fiorenzi, Eureka County, NV
A. Johnson, Eureka County, NV
A. Remus, Inyo County, CA
M. Yarbro, Lander County, NV
R. Massey, Lander County, NV
J. Pitts, Lincoln County, NV
M. Baughman, Lincoln County, NV
A. Funk, Mineral County, NV
J. Shankle, Mineral County, NV
L. Bradshaw, Nye County, NV
M. Murphy, Nye County, NV
J. McKnight, Nye County, NV
D. Weigel, GAO
W. Barnard, NWTRB
R. Holden, NCAI
A. Collins, NIEC
R. Arnold, Pahrump Paiute Tribe
J. Larson, White Pine County
R. Clark, EPA
F. Marcinowski, EPA
R. Anderson, NEI
R. McCullum, NEI
S. Kraft, NEI
J. Kessler, EPRI
D. Duncan, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
J. Curtiss, Winston & Strawn
S. Echols
N. Rice, NV Congressional Delegation
T. Story, NV Congressional Delegation
J. Reynoldson, NV Congressional Delegation
S. Joya, NV Congressional Delegation
J. Pegues, City of Las Vegas, NV
L. Lehman, T-REG, Inc.

I. Zabarte, W.S.N.C.

C. Anderson, Las Vegas Paiute Tribe

J. Birchim, Yomba Shoshone Tribe

L. Jackson, Timbisha Shoshone Tribe

C. Meyers, Moapa Paiute Indian Tribe

V. Miller, Fort Independence Indian Tribe

A. Bacock, Big Pine Paiute Tribe of the Owens Valley

R. Quintero, Inter-Tribal Council of Nevada (Chairman, Walker River Paiute Tribe)

M. Bengochia, Bishop Paiute Indian Tribe

J. Egan, Egan & Associates, PLLC

R. Bahe, Benton Paiute Indian Tribe

C. Bradley, Kaibab Band of Southern Paiutes

R. Joseph, Lone Pine Paiute-Shoshone Tribe

L. Tom, Paiute Indian Tribes of Utah

E. Smith, Chemehuevi Indian Tribe

J. Charles, Ely Shoshone Tribe

D. Crawford, Inter-Tribal Council of Nevada

H. Blackeye, Jr., Duckwater Shoshone Tribe

D. Eddy, Jr. Colorado River Indian Tribes

J. Leeds, Las Vegas Indian Center

W. Briggs, Ross, Dixon & Bell

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-02-01

"OBSERVATION AUDIT OF THE

BECHTEL SAIC COMPANY, LLC

AUDIT NO. BSC-SA-01-30 OF Lambda Research, Inc."

/RA/ 11/08/01
Ted Carter
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

/RA/ 11/08/01
Robert D. Brient
Center for Nuclear Waste Regulatory Analyses

Reviewed and Approved by:

/RA/ 11/27/01
N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

1.0 INTRODUCTION

1.1 Lambda Research, Inc. (Background)

The current "Statement of Work Agreement" between the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Management and Operating Contractor (M&O) and Lambda Research, Inc (Lambda) is Bechtel SAIC Company, LLC (BSC) Purchase Order 24540-000-TSA-0005, Rev. 1, and the "Technical Services Statement of Work for Lambda Research Incorporated, Revision 03," dated September 24, 2001.

The scope of Lambda's work under the current statement of work is to measure residual stresses of welded mockups of selected materials related to the high-level waste container design for the proposed repository at Yucca Mountain, Nevada.

1.2 Performance of the Audit

Staff from the U.S. Nuclear Regulatory Commission (NRC), Division of Waste Management, and the Center for Nuclear Waste Regulatory Analyses Center (CNWRA) observed the M&O, BSC, audit BSC-SA-01-30 of activities regarding the implementation of Lambda's Quality Assurance Manual (QAM). This audit was conducted on October 31 through November 1, 2001, at Lambda's facilities in Cincinnati, Ohio.

The purpose of this audit was to evaluate the effectiveness of the implementation of Lambda's QAM, and to determine if applicable requirements of the OCRWM Quality Assurance Program Description (QARD) were being met. The scope of the audit included evaluating the implementation of the QARD and QAM for residual stress measurements supporting the design of the high-level waste containers for the proposed repository at Yucca Mountain, Nevada.

The NRC observers' (observers') objective was to assess whether BSC Quality Assurance (QA), Product Quality Engineering/Supplier Audits and Evaluation Section, audit team (audit team) and Lambda were properly implementing the QA requirements contained in Subpart G, "Quality Assurance," to Part 60, of Title 10 of the U.S. Code of Federal Regulations (10 CFR Part 60) and the provisions contained in the QARD. Before the start of the audit, the audit team and observers were given a tour of the Lambda facility.

This report presents the observers' determination of the effectiveness of the BSC audit and whether Lambda implemented adequate QARD and QAM controls in the audited areas.

2.0 MANAGEMENT SUMMARY

Within the areas evaluated, the audit team identified several minor potential deficiencies. These deficiencies did not appear to impact the quality and technical adequacy of the Lambda products being supplied to BSC. The audit team identified the potential deficiencies during the audit regarding training, calibration (i.e., measuring and test equipment) controls, document controls, software controls, and corrective action.

BSC had previously identified an open item regarding the statement of work requirement to destructively test representative samples of strain gages used in the measurements, so as to confirm their performance characteristics. This item was discussed with Lambda management during the audit.

The observers determined that BSC Audit No. BSC-SA-01-030 was well-planned and effectively executed. The audit team members were independent of the activities they audited and were

knowledgeable regarding the QA and technical disciplines within the scope of the audit. The audit team members' qualifications were reviewed and were found acceptable.

The audit team concluded that the QARD and QAM had been satisfactorily implemented in the areas evaluated. The potential deficiencies identified did not appear to have a significant potential to adversely affect the validity of the residual stress measurements. The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. The staff will continue to interface with OCRWM and follow the progress that Lambda is making to address the issues identified during this audit.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Ted Carter	Team Leader	NRC
Robert D. Brient	QA Specialist	CNWRA

3.2 BSC Audit Team

Robert F. Hartstern	Audit Team Leader	BSC QA
Richard L. Hand	Auditor	BSC QA
Ahmed Monib	Technical Observer	BSC

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This BSC QA audit of Lambda was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Performance/Deficiency Reporting." The NRC staff's observation of this audit was based on NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Scope of the Audit

The scope of the audit included evaluating the implementation of the QARD and QAM for the residual stress measurements supporting the design of the high-level waste containers for the proposed repository at Yucca Mountain, Nevada. The audit was programmatic in nature, and evaluated the QA requirements contained in Subpart G of 10 CFR Part 60,, QARD Supplement II, "Sample Control," and QARD Supplement V, "Control of Electronic Management of Data."

4.2 Conduct and Timing of the Audit

The audit was performed effectively and the audit team demonstrated a sound knowledge of the applicable requirements. The audit checklist was developed using the QARD and the Lambda QAM. Applicable Lambda implementing procedures were evaluated during the audit. Audit team members conducted thorough interviews; they challenged and clarified responses when appropriate; and they effectively employed their detailed audit checklist. The observers concluded that the timing of the audit was appropriate for the auditors to evaluate completed and anticipated residual stress measurement activities for BSC. The audit team and the observers caucused at appropriate times. A meeting between the audit team and Lambda (with the observers present) was held after the completion of the first audit day, to discuss the current audit status and preliminary findings.

4.3 Audit Team Qualification and Independence

The qualifications of the audit team had been previously reviewed for accuracy and completeness in accordance with the requirements of DOE Procedure QAP 18.1, "Auditor Qualification." The observers concluded that the audit team members had the necessary expertise to perform the audit and were qualified to audit Lambda's activities and that the audit team members were independent of the audited activities.

4.4 Examination of QA Elements

4.4.1 Audit Approach

The audit team interviewed Lambda QA, engineering, supervisory, laboratory, and Lambda technical/management staff. Current laboratory activities were observed and the BSC welded mockup was examined. The audit evaluated the activities and records for the two Lambda work orders for stress measurements taken on the welded mockup, using ASTM E837 hole drill and ring-core methods. The residual stress measurement processes from receipt of the mockup through completion of the test reports were followed during the audit. In addition, the overall adequacy and implementation effectiveness of the Lambda quality program was assessed.

4.4.2 Audit Findings

Lambda's quality system had been certified as meeting ISO 9002:1994 ("Quality systems - Model for quality assurance in production, installation, and servicing") and has been accredited to ISO Guide 25 ("General requirements for the competence of calibration and testing laboratories") by third-party agencies. The quality system is organized following ISO Guide 25. During preparation of their checklists and for cross-reference use during the audit, the auditors sorted the Lambda quality system elements according to the Part 60, Subpart G criteria. This was an effective approach for determining whether the quality system designed for ISO 9002 and Guide 25 met QARD requirements.

Lambda's program included an extensive array of quality system and laboratory test procedures. The auditors thoroughly reviewed quality system procedures and laboratory procedures directly associated with the residual stress measurements. These procedures and their implementation were discussed with appropriate Lambda staff.

4.4.3 Potential Deficiencies

Potential deficiencies (i.e., subject to concurrence by BSC QA management) were identified by the audit team as follows:

Training

- No evidence was available of required training for the Laboratory Supervisor.
- Discrepancies were identified between the QAM and two procedures regarding training requirements for Laboratory Technicians.

The observers agreed with the audit team's findings in this area.

Measuring and Test Equipment Control

- No impact evaluation had been performed for gauge blocks found to be out-of-tolerance (in November 2000). The required Out-of -Tolerance report was not prepared.
- Calibration records lacked required "next calibration due date," and several had no approval signature.

- The form/schedule used for calibration recall and other scheduled verifications had no year indicated.

The observers agreed with the audit team's findings in this area.

Document Control

- Several procedure titles and revision numbers disagreed between the procedure index and procedures.
- Strain gauge lot numbers had not been recorded on test data forms for unambiguous traceability regarding individual tests and the measuring equipment used.

The observers agreed with the audit team's findings in this area.

Software Verification and Validation

- Purchased software "ReStress" had no evidence of the testing (verification and validation) required by Procedure 3P4001_2.
- Verification and validation data for the in-house-developed software "Trecalc" did not identify the version number of the software, the date of the tests, or the individual performing the tests.

The observers agreed with the audit team's findings in this area.

Corrective Action

- QA Incident Reports had not been initiated as soon as the conditions were identified.
- No log had been used to identify and track open items requiring corrective action.
- Corrective actions did not appear to have been resolved on timely bases.

The observers agreed with the audit team's findings in this area.

5.0 NRC STAFF FINDINGS

The observers determined that Audit No. BSC-SA-01-030 was effective in determining the level of compliance of Lambda's activities associated with residual stress measurements. The observers agreed with the audit team's conclusion that the QARD and QAM had been satisfactorily implemented except for the identified potential deficiencies.

5.1 NRC Audit Exit Summary

During the audit exit, the observers stated that they agreed with the audit team findings and recommendations as presented at the audit exit meeting.

5.2 NRC Audit Observer Inquiries

There were no Audit Observer Inquires (AOIs) written during this audit.

5.3 NRC AOI from Previous NRC Observation

The following AOI, from a previous DOE audit observed by NRC, is closed:

> AOI No. M&O-APR-01-02-4, dated February 9, 2001, was written to identify an observer inquiry for ANL-NBS-HS-00032. The AOI states: "The work upon which this model is

based (Flint, et al., 1996, "Conceptual and Numerical Model of Infiltration at Yucca Mountain") is unqualified. (See OCRWM QA Audit Report M&O APR-00-04)(p. 9). Was information used to support conclusions made in the Infiltration AMR? If yes, describe how the Flint, et al. (1996) data were qualified and assumptions verified. NRC requests additional information and details. (Refer to U.S. NRC's Observation Audit Report No. OAR-00-04)."

AOI M&O-APR-01-02-4 has been closed based on DOE's response to this AOI, as provided in a letter from S. Brocoum to C.W. Reamer, dated August 16, 2001. The NRC reviewed the letter and determined that the DOE response to this AOI was satisfactory. The NRC considers the status of AOI M&O-APR-01-02-4 to be closed.